Supreme Court, U.S.
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No. 98-1536

In The

Supreme Court of the United States

October Term, 1998

Randon Bragdon, D.M.D.,

Petitioner,

v.

Sidney Abbott *et al.*,

Respondents,

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

Brief of Amicus Curiae of Congressman Charles Norwood, D.D.S., Congressman Tom Coburn, M.D., The American Association of Forensic Dentists, The Association of American Physicians and Surgeons, Dentists for Preservation of Professional Judgment, E.J. Neiburger, D.D.S., Cary Savitch, M.D., Stephen D. Carter, D.D.S., John L. Kennedy D.D.S., Charles E. Smith, D.M.D., Brian E. Eifert, M.D., William J. Dubose, D.M.D, and Robert J. Gherardi, D.M.D in Support of Petitioner Randon Bragdon, D.M.D.

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QUESTIONS PRESENTED

1. Did the First Circuit Court of Appeals err in denying a trial on the merits where there is a question of material fact of whether there is a "direct threat" to the health of the health care worker or other person as determined by the health care professional pursuant to 42 U.S.C. § 12182 (b)(3)?

2. Did the scientific evidence that was available in 1994 evidence a "direct threat" to the health care worker or other person within the meaning of 42 U.S.C. § 12182 (b)(3)?

3. Did the First Circuit Court of Appeals err in denying a trial on the merits which would have produced "current" and "best available" post-1994 evidence of "direct threat" to the health care worker and other person when treating HIV-infected patients pursuant to 42 U.S.C. § 12182 (b)(3)?

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29 *American Dental Association News*, March 16, 1998, at 19 8

INTEREST OF THE *AMICI*[1]

This brief represents the interests of Congressman Norwood, who is a dentist, and Congressman Coburn, who is a physician. This brief also represents the interests of dentists, physicians, medical/dental-related professionals and other persons who have a direct professional and health interest in the outcome of this litigation. The outcome is professional to them, because they are health care professionals engaged in rendering health care to their patients, including those infected with HIV. Secondly, and perhaps more importantly, as natural persons, notwithstanding the fact they are health care professionals, they are susceptible themselves to HIV infection when invasively treating patients with HIV infectious disease.

The matters contained in this brief are relevant to this litigation, because the litigation will ultimately be partially responsible for formulating medical standards required of health care professionals when rendering care to HIV-infected persons. Such persons have been found by the court in this case to be disabled under the Americans with Disabilities Act ("ADA") 42 U.S.C. § 12101 (1994). While such persons may be disabled as a matter of law, the guiding principles for application of the law must be pursuant to sound medical and scientific evidence and not the mere conclusions by the First Circuit Court of Appeals in *Abbott* v. *Bragdon*, 163 F.3d 87 (1st Cir., 1998).

The potential infectious condition of patients constitutes a "direct threat" to the persons who make up these *Amici*. It is in the interest of these *Amici* to ask the United States

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[1] The parties have consented to the filing of this brief and consents have been filed with the Court. This brief was authored by A. Eric Johnston, Esquire, with the help of *Amici*. It was not authored by counsel for any party. No person or entity other than *Amici* have made any monetary contribution hereto.

Supreme Court to accept the *Writ of Certiorari* of Dr. Randon Bragdon, which asks for a trial to determine the material facts concerning the "direct threat" issue in this case.

SUMMARY OF ARGUMENT

This brief concerns itself with three aspects of the "direct threat" issue: 1) the legal aspect; 2) the scientific question in 1994; and 3) post-1994 ongoing scientific findings relevant to the issue of "direct threat."

First, there is still a question of material fact concerning the issue of "direct threat." Summary judgment, as exercised by the District Court and confirmed by the First Circuit Court of Appeals, denied a trial where scientific questions of fact can be investigated to the necessary depth. *Abbott* v. *Bragdon*, ibid; *Abbott* v. *Bragdon*, 107 F.3d 934 (1st Cir. 1997).

Secondly, science in 1994 supported the reasonable professional judgment of Dr. Bragdon when he recommended to Ms. Abbott that her invasive dental healthcare treatment be performed in the hospital operating room.

Thirdly, if this case is remanded for trial, not only will substantive, in-depth evidence of science and medicine be adduced, but important post-1994 medical information on "direct threat" not heretofore considered by the Court will be brought to the Court's attention.

Most of the scientific submissions for this brief are extensive and divided into four categories located in the Appendices. The categories represent the health interests of all four groups affected by the issue of "direct threat": 1)

dental patients with HIV infectious disease; 2) other non-infected dental patients; 3) dental assistants/hygienists; and 4) dentists themselves.

By recommending that any patient with HIV infectious disease, regardless of the stage of the disease, have invasive dental healthcare procedures performed in the hospital operating room, this brief argues that Dr. Bragdon was prudent in 1994—and would still be today.

ARGUMENT

Contrary to the Centers for Disease Control and Prevention's ("CDC") claim that "universal precautions" are totally sufficient to prevent the spread of disease, there are significant inadequacies in those precautions. Also, the "passive surveillance" system used by the CDC can only contribute to deficient sampling and incorrect scientific conclusions. Though universal precautions are prudent, they should only constitute the minimal infection control guidelines, instead of the maximum.

I. Did the First Circuit Court of Appeals err in denying a trial on the merits where there is a question of material fact of whether there is a "direct threat" to the health of the health care worker or other person as determined by the health care professional pursuant to 42 U.S.C. § 12182 (b)(3)?

On June 25, 1998, the U.S. Supreme Court remanded the "direct threat" issue to the U.S. First Circuit Court of Appeals to determine, as a matter of fact, whether there is a "direct threat" when a dentist invasively treats a known patient with HIV infectious disease. *Bragdon* v. *Abbott* ___ U.S. ___ 118 S.Ct. 2196, 141 L.Ed. 2d 540 (1998). On December 29, 1998, the First Circuit Court of Appeals ruled

on the case as a matter of law, by affirming previous summary judgment, rather than returning it to the trial court to examine the overwhelming scientific evidence related to the case. *Abbott* v. *Bragdon*, 163 F. 3d 87 (1st Cir. 1998).

The First Circuit Court of Appeals says there is no question of material fact in dispute. There is no evidence in its December 29, 1998, written judgment that any of the scientific findings submitted in three separate briefs filed on behalf of Dr. Bragdon were even considered.

The standards for Summary Judgment are well known. *Celetex* Corp v. *Catrett*, 477 U.S. 317, 106 S. Ct. 2548, 91 L.Ed. 2d. 264 (1986). In this litigation the Courts have addressed the legal issues, but not sufficiently the factual issues. As a matter of law, summary judgment includes a factual finding aspect. That aspect has not been addressed by the First Circuit Court of Appeals. It has ruled only on the written filings from the summary judgment proceeding.

The Circuit Court's ruling on remand, *Abbott* v. *Bragdon*, ibid, merely reviewed the CDC guidelines and American Dental Association policies without taking evidence as to their scientific accuracy and support in the medical community. While the guidelines and policies are themselves evidence, there should be thorough and sifting examination and cross-examination of all evidence in order to determine scientific and medical accuracy. Legal niceties cannot be observed with final and binding judgments based on conclusions when they address a significant and life-threatening disease and protective procedures.

The appendices hereto suggest the significant scientific information available for the Courts to make complete and necessary findings so that medical science and health care are not compromised by legal procedures. The applicable

regulations seek to avoid such mistakes by requiring that a determination of whether there is a direct threat be based on "current medical knowledge or on the best available objective evidence." 28 C.F.R. 36.208 (c) (1996).

The initiating event was Ms. Abbott's 1994 visit to Dr. Bragdon. This is not a damage case for what occurred at that time; rather it was the initiation of a legal determination of, in effect, an applicable standard of care to be observed by health care professionals. Therefore, the time cannot be related to 1994 and earlier, but post-1994 medical evidence must be submitted. Consequently, based on the directions of this Court on its remand, a full and complete trial must be had for the examination of material facts, so the public and health care professionals will be served in the future.

The Court is reminded of Justice Ginsburg's concurring statement:

> I further agree, in view of the "importance [of the issue] to health care workers," *ante*, at 2213, that it is wise to remand, erring, if at all, on the side of caution. By taking this course, the Court insures a fully informed determination whether respondent Abbott's disease posed "a significant risk to the health or safety of [petitioner Bragdon] which [could not] be eliminated by a modification of policies, practices, or procedures...." 42 USC 12182(b)(3). *Bragdon* v. *Abbott*, 118 S.Ct. 2196, 2214 (1998).

II. Did the scientific evidence that was available in 1994 evidence a "direct threat" to the health care worker or other person within the meaning of 42 U.S.C. § 12182 (b)(3)?

The First Circuit Court of Appeals ruled there is not a "direct threat" when a dentist invasively treats a known

patient with HIV infectious disease. However, the scientific evidence proves otherwise.

"Universal precautions" are infection control guidelines recommended by CDC and the American Dental Association. Scientific findings proving the ineffectiveness of latex gloves (recommended as part of universal precautions) demonstrated that there exists a small but significant "degree of risk" when treating patients with HIV infectious disease in the dental office. Latex gloves are porous and can leak.[2] There are numerous cases of Hepatitis B viruses (HBV) passing through latex gloves from health care worker to patient and from patient to health care worker.[3] HBV and HIV are very similar. Latex gloves cannot stop a needle-stick or other sharp dental instruments from injuring the hand. *This is the most common cause of occupational AIDS transmission.*[4] The most recent brief filed by Dr. Bragdon to the First Circuit Court of Appeals demonstrates the significance and prevalence of needle-stick injuries to the dentist.[5] This information was from Dr. David Bell (the CDC's Director of the HIV Infection Programs) and Dr. Sanford Kuvin (Dr. Bragdon's expert witness). The risk of a dentist contracting HIV infectious disease is in the range of 1 in every 67,000 shots (intra-oral injections) administered to

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[2] Lattau, L. et al. "Transmission of Hepatitis B with Resultant Restriction of Surgical Practice." *Journal of the American Medical Association.* 255. February 21, 1986, page 934.

[3] Reingold, Authur, L. et al. "Failure of gloves and other protective devices to prevent the transmission of Hepatitis B Virus to oral surgeons." *Journal of the American Medical Association.* 259. May 6, 1988, pages 2558-2560.

[4] "Occupational Exposure to Bloodborne Pathogens: Final Rule." *Federal Register.* Vol.. 56, No. 235. Dec. 6, 1991, page 64016.

[5] *Amicus* Brief of Defendant/Appellant Randon Bragdon, D.M.D., to the United States Court of Appeals for the First District, on Remand from the United States Supreme Court, pages 5-6.

patients. Those in the medical and dental profession who are aware of these facts believe this is a significant statistic.

Universal precautions were also intended to protect the non-infected dental patient from HIV infectious disease. Dr. Bragdon dealt with the concern for the safety of his other non-infected patients when planning his treatment for Ms. Abbott. Since Ms. Abbott was *a known patient with HIV infectious disease*, Dr. Bragdon concluded that to treat Ms. Abbott utilizing universal precautions in the hospital operating room would not only *reduce* the possibility of patient-to-patient HIV infection, but effectively *eliminate* it.

In 1994, Dr. Bragdon was also faced with a persuasive recommendation—the 1991 OSHA recommendation that "universal precautions" are not sufficient to protect dental health care worker-employees, and prudent additional precautions should be utilized.[6] This OSHA recommendation is still in effect. Dr. Bragdon considered the safety of his dental assistant. He was correct that the distractions and required stressful time schedules of daily private dental practice could be altered in the hospital operating room environment. This option would be safer, because potential needle-sticks and sharp instrument injuries to his dental assistant could be minimized.

Dr. Bragdon also considered his own safety for the same reasons he considered the safety of his dental assistant. He loves his family. Their welfare is at stake when his safety is at stake. It is always prudent to further reduce the degree of risk when possible.

The CDC formulates universal precaution guideline recommendations not by comprehensive and complete

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[6] "Occupational Exposure to Bloodborne Pathogens: Final Rule." *Federal Register.* Vol. 56, No. 235. Dec. 6, 1991, page 64088.

scientific epidemiological studies, but by their admitted irregular and unreliable system of accumulating information, called "passive surveillance." The *ADA News* (American Dental Association) reported that "CDC officials cite the shortcomings of the current AIDS surveillance system.... Minus a clear and full picture of HIV trends, government officials cannot devise effective prevention and treatment programs."[7] The CDC accepts any information that comes its way, but has no comprehensive or scientific method of obtaining data in which to formulate anything more than a *recommendation* of proposed infection control guidelines. Consequently, the "passive surveillance" system used by CDC accumulates deficient, incomplete and unreliable epidemiological data concerning the "degree of risk" of HIV infection for non-infected patients, dental assistants/ hygienists and dentists. No standard "degree of risk" of HIV infection, based on sound and comprehensive scientific findings, was established in 1994. One has yet to be established by the CDC or the American Dental Association.

The scientific community has used and continues to use various words to describe the "degree of risk"—words such as "small" or "very small." Any small degree of risk to a dentist is significant and should be further reduced when possible because he/she is facing the possibility of terrible suffering and certain premature death by contracting HIV infectious disease from an infected patient.

Dr. Bragdon received a recommendation from a reputable dental professional organization concerning the invasive dental healthcare treatment environment and other additional prudent precautions when invasively treating known patients with HIV infectious disease. In 1992, the American Association of Forensic Dentists had researched

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[7] *ADA News.* Volume 29, No. 6. March 16, 1998, page 19.

the issue of hospital versus private office treatment. The Committee recommended hospital dental treatment and other protective actions if the dentist found this to be in his/her patient's and/or his/her best interests.[8]

III. Did the First Circuit Court of Appeals err in denying a trial on the merits which would have produced "current" and "best available" post-1994 evidence of "direct threat" to the health care worker and other person when treating HIV-infected patients pursuant to 42 U.S.C. § 12182 (b)(3)?

In summary judgment on December 22, 1995, Judge Brody stated, "The position taken by Defendant is not an unreasonable one. The court is sensitive to Defendant's concerns about the possibility of the transmission of HIV infectious disease from patient to him, his staff, and other patients, "*particularly in light of how much science has yet to learn about HIV*" (emphasis added).[9] On March 5, 1997, the First Circuit Court of Appeals stated, "We also recognize that cases of this kind are *fact-sensitive*..." (emphasis added). Justice Ginsburg's concurring statement noted above also states the importance of obtaining all relevant facts. All courts inferred that they were open-minded to science as it related to the direct threat issue and question of material fact. The lack of consideration of the relevant post-1994 ongoing science by the First Circuit Court of Appeals proves otherwise and is in direct opposition to the statutory intent requiring "current" and "best available evidence." 28 C.F.R. 36.201 (c) (1996).

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[8] "New AAFD AIDS/HIV Policy Recommendation." *Journal of the American Association of Forensic Dentists.* Vol. 15s, No. 7-9, page 3.

[9] United States District Court, District of Maine, Ruling in *Sidney Abbott* v. *Randon Bragdon, D.M.D.* Dec. 22, 1995, page 26.

For example, according to a CDC 1996 recommendation, post-exposure prophylactic drugs must be administered within the crucial one-hour window after an occupational exposure to HIV infectious disease in order to reduce by 79% the possibility of contracting HIV.[10] Dr. David K. Henderson of the National Institutes of Health, made the following statement in a recent issue of the *Journal of the American Medical Association*:

> As promptly as feasible, the health care worker should report the exposure to her/his institution's occupational medical department...If prophylaxis is elected, the first dose should be administered as promptly as possible. *We strive to administer the first dose within 1 hour of the exposure* (emphasis added).[11]

Today, the recommendation is still that one should be administered these post-exposure prophylactic drugs as quickly as possible after an occupational exposure to HIV infectious disease. Occupational exposures should be considered "urgent" medical concerns to ensure timely administration of post-exposure prophylactic drugs.[12] These drugs are usually readily available in the hospital and are not available in any dental office. Because of the availability of these drugs only in the hospital, it is prudent to invasively treat known patients with HIV infectious disease in the hospital operating room in the event a dentist or dental assistant receives an occupational exposure. Furthermore, the CDC has stated that "The risk per episode of percutaneous

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[10] *Morbidity and Mortality Weekly Report* by the Centers for Disease Control and Prevention. Vol. 45, No. 22. June 7, 1996, page 470.

[11] Henderson, Dr. David K.,"Postexposure Chemoprophylaxis for Occupational Exposures to the Human Immunodeficiency Virus." *Journal of the American Medical Association.* Vol. 281, No.10. 10 March 1999, page 931.

[12] *Morbidity and Mortality Weekly Report* by the Centers for Disease Control and Prevention. Vol. 47, No. RR-7. May 15, 1998, page 1.

injury (e.g., a needle stick) to HIV-infected blood is estimated at 0.4% (upper limit of 95% confidence interval = 0.8%)."[13] This figure could be reduced when performing invasive treatment in a hospital operating room because the advantages of the operating room allow maximum treatment time and concentration.

This post-exposure prophylactic drugs science (post-1994 science) is one of the most important of all discoveries related to the issue of "direct threat", yet it was not considered relevant by the First Circuit Court of Appeals when presented to them in a brief supporting Dr. Bragdon.[14]

CONCLUSION

For the foregoing reasons, it is requested that the U.S. Supreme Court accept Dr. Bragdon's petition for a Writ of *Certiorari* which asks for a trial for the full in-depth investigation of the many scientific findings relevant to the issue of "direct threat."

Respectfully submitted,

A. Eric Johnston, Esq.

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[13] *Morbidity and Mortality Weekly Report* by the Centers for Disease Control and Prevention, Vol. 47, No. RR-17, September 25, 1998, page 3.

[14] *Amicus Curiae* Brief by the American Association of Forensic Dentists to the United States Court of Appeals for the First Circuit. September 29, 1998, pages 9,16,17.

APPENDICES

APPENDIX A

THE INTERESTS OF THE HEALTH OF PATIENTS WITH HIV INFECTIOUS DISEASE WHEN INVASIVE PROCEDURES ARE PERFORMED BY A DENTIST

1) 1994 scientific findings show that Ms. Sidney Abbott was significantly immune-compromised when she visited Dr. Bragdon, proving that Dr. Bragdon was prudent and reasonable in his decision to perform invasive dental procedures on Ms. Abbot in a hospital operating room. These findings were submitted to the First Circuit Court of Appeals in an Amicus *Curiae* Brief in September, 1998.[1]

Dr. Bragdon reported to Judge Morton A. Brody the status of Ms. Abbott's impaired immune system, but this fact was not considered in summary judgment by the United States First Circuit Court of Appeals in its December 29, 1998, ruling. The courts have yet to consider the overall health interests of Ms. Abbott. The courts have only ruled on the civil right, as a matter of law, that gives Ms. Abbott the legal right to be protected from the recommendation of her dentist that she be treated in the cleanest and safest environment in the world—the hospital operating room.

It is acknowledged that the potential for a patient with early onset of HIV infectious disease to acquire an opportunistic infection is small—but it is significant.

The significance of the *consequences* is the issue, not just the "small" probability of a patient with HIV infectious disease

acquiring an opportunistic infection when invasively treated routinely in a dental office as opposed to treatment in the

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[1] Amicus *Curiae* Brief of Dentists for Preservation of Professional Judgement, September, 1998, pages 5-8, 19, 20, 24, 25.

hospital operating room, where infection control is maximized and the potential for opportunistic infections is minimized. The 1994 *Harrison's Principles of Internal Medicine*, thirteenth edition, states:

> It is estimated that approximately 50-70 percent of individuals with HIV infection experience an acute syndrome approximately 3 to 6 weeks following primary infection. Opportunistic infections have been reported during this stage of infection. (Page 1587)
>
> Certain patients will remain entirely asymptomatic despite the fact that their CD+ T cell counts fall to extremely low levels. Certain patients, otherwise asymptomatic, develop persistent generalized lymphadenopathy. With few exceptions, there is a progressive diminution of CD4 + T cell counts during the asymptomatic period, which ultimately leads to a state of immunosupression." (Page 1588)
>
> Neurologic problems occur throughout the course of the disease and may be inflammatory, demyelinating, or degenerative in nature. Virtually all patients with HIV infection have some degree of involvement of the nervous system with HIV. This is evidenced by the fact that cerebrospinal fluid findings are abnormal in approximately 90 percent of patients, even at the asymptomatic stage of HIV infection. (Page 1589)
>
> Candida infections are the most common fungal infections occurring in patients with HIV infection.
>
> Infections are often seen early in the course of HIV infection. (Page 1600)

> Over 95 percent of HIV-infected patients have evidence of infection with hepatitis B: coinfection with hepatitis C and hepatitis D is also quite common. (Page 1607)

> Pulmonary disease is seen in virtually every patient with HIV infection. The most common manifestation of pulmonary disease is pneumonia, and the most common cause of pneumonia is *Pneumocystis carinnii*. In addition to pneumonia, sinusitis is a common respiratory tract complication of HIV infection and is seen at all stages of infection. (Page 1604)

> Hematologic problems are common throughout the course of HIV infection. Anemia is the most common hematologic abnormality seen with HIV infection and is present in 18% of asymptomatic seropositive individuals, 50% of patients with early symptoms, and 75% of patients with AIDS. (Page 1608)

2) Post-1994 Scientific Findings Prove That Ms. Sidney Abbott was significantly immune-compromised when she visited Dr. Bragdon:

In 1994, the risk to Ms. Sidney Abbott's health was well established. We note pages 3 through 6 of the *Amicus Curiae* Brief submitted to the U.S. Supreme Court in *Bragdon* v. *Abbott* by the Infectious Disease Society of America, *et al.* This brief states:

> From the onset of infection, HIV is a serious medical impairment.... Even in patients who are in the early stages of HIV infectious disease, the virus is causing a wide variety of laboratory

> abnormalities.... Moreover, even outwardly asymptomatic patients are at increased risk for a number of very serious medical conditions including mycobacterium tuberculosis, syphilis, acute and chronic hepatitis, toxoplasma *gondii*, and pneumocystis *carininii* pneumonia.

The use of the hospital operating room was a reasonable medical option to protect Ms. Abbott from contracting opportunistic infectious diseases to which she was vulnerable when she visited Dr. Bragdon's office. The American Medical Association's Amicus Brief to the U.S. Supreme Court states:

> This second stage of HIV disease is known as early, or asymptomatic, HIV disease.... A consistent pattern of irregularities in the blood and immune systems can also be detected with laboratory tests. Finally, a range of dermatological abnormalities and oral lesions are not uncommon during this phase. *This stage of the disease requires consistent monitoring and routine medical care to prevent, so far as is practicable, the onset of opportunistic infections* (emphasis added). (pages 7 and 8)*

We have demonstrated our concern that *all* patients with HIV infectious disease be treated with compassion and with current scientific knowledge dictating all treatment plans. This makes the option for invasively treating patients with HIV infectious disease in the hospital operating room reasonable and prudent. This protocol could protect the significantly immune-compromised patient with HIV infectious disease from unnecessary opportunistic infections common in the dental office (e.g. colds, flu, upper respiratory infections, etc).

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* Amicus Curiae Brief of the American Medical Association, at 7, 8, Baragdon b. Abbott, 118 S.Ct. 2196 (1998)

APPENDIX B

THE INTERESTS OF THE HEALTH OF THE NON-INFECTED PATIENTS WHEN A DENTIST TREATS A KNOWN PATIENT WITH HIV INFECTIOUS DISEASE

The CDC and the American Dental Association intend universal precautions to "reduce" the possibility of HIV infection from being contracted by non-infected patients. If a known patient with HIV infectious disease is treated in the hospital operating room instead of the dental office, the possibility of that patient passing HIV infectious disease to a non-infected patient is not reduced, but eliminated. Dr. Bragdon was aware of the relevance of the Acer case. Dr. David Acer gave HIV infectious disease to six of his patients, although he used universal precautions.[2] This case alone caused many dentists to question the effectiveness of universal precautions.

There is also concern about dentists and other dental healthcare workers performing invasive procedures on non-infected patients *without* the non-infected patients having knowledge of the HIV positive status of the dentist.

It is an open policy of the American Dental Association to support the non-disclosure of HIV positive dentists who invasively treat non-infected patients, including children.[3]

The principle of informed consent involves explaining *all* the risks possible when the invasive procedure is performed. We believe the risk, no matter how small, of transferring

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[2] Ciesielski, C. "Transmission of HIV in a Dental Practice." *Annals of Internal Medicine.* Vol. 116, No. 10. May 15, 1992, pages 798-805.
[3] *ADA News.* Vol. 29, No. 4. March 16, 1998, page 19.

HIV infectious disease from a dental health care worker to a non-infected patient should be disclosed before patients give their consent to the invasive procedure. The policy of withholding a dentist's HIV-positive status from the patient is not fair to all concerned. The continual overconfidence and overstatement of the effectiveness of universal precautions has led the American Dental Association to the inappropriate conclusion that dental patients do not have the right to know that their dentists have HIV infectious disease.

Two court rulings have addressed this issue and ruled in favor of the non-infected patient:

> *Scoles* v. *Mercy Health Corp.*, 1994 W. L. 686623 (Universal precautions failed to satisfactorily reduce the threat of transmission posed by an HIV-infected surgeon, due to the fatal nature of HIV), which settled before appeals.
>
> *Mauro* v. *Borgess Medical Center*, 886 F. Supp. 1349. (W.D. Mich. 1995). (HIV infected surgical technician posed a direct threat because of the "real possibility of transmission, however small, and because the consequence of transmission is invariably death").

APPENDIX C

THE INTERESTS OF THE HEALTH OF THE DENTAL ASSISTANTS/HYGIENISTS WHO PERFORM INVASIVE DENTAL PROCEDURES FOR KNOWN PATIENTS WITH HIV INFECTIOUS DISEASE

Scientific findings prove that the hospital operating room can be the best invasive treatment environment not only for many patients with HIV infectious disease, but also for the dental assistants/hygienists.

Since 1994, medical advances have been made which significantly extend the lives of patients with HIV infectious disease if administered in a proper and timely manner. These modern drug "cocktails" have also proven effective in stopping the infection for someone who has been exposed to the virus. These drugs are called post-exposure prophylaxis drugs (PEP drugs). The Centers for Disease Control reported in 1996 that if an injured dentist or dental assistant/hygienist receives PEP drugs within one hour after an occupational HIV exposure, the possibility that he/she will contract HIV infectious disease is reduced by about 79%. "PEP should be initiated promptly, preferably within 1-2 hours postexposure."[4] This urgent need for the timely administration of PEP drugs following an exposure to HIV infectious disease is still recommended by the CDC.[5] If a dental healthcare worker is occupationally exposed to HIV infectious disease, it is best that he/she is exposed while working in a hospital operating room due to instant availability of the PEP drugs.

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[4] *Morbidity and Mortality Weekly Report* by the Centers for Disease Control and Prevention. Vol. 45, No. 22. June 7, 1996, page 470.

[5] *Morbidity and Mortality Weekly Report*. Vol. 47, No RR-7. May 15, 1998, page 1.

Dr. David K. Henderson of the National Institutes of Health, made the following statement in a recent issue of the *Journal of the American Medical Association*:

> As promptly as feasible, the health care worker should report the exposure to her/his institution's occupational medical department...If prophylaxis is elected, the first dose should be administered as promptly as possible. *We strive to administer the first dose within 1 hour of the exposure* (emphasis added).[6]

The downside of the anti-HIV drugs is that drug-resistant human immuno-deficient viruses (HIV) have come into existence. The mutated viruses void any extension of life realized by utilizing the modern treatment "cocktails." This has further significantly raised the anxiety level of many healthcare workers who perform invasive procedures for known patients with HIV infectious disease.

Dr. Bragdon's decision in 1994 was supported by 1994 scientific data, has since been further endorsed by post-1994 scientific data (including the discovery and use of PEP drugs), and was non-discriminatory and fair to all concerned. He demonstrated prudent clinical judgment when suggesting to Ms. Abbott that she have her invasive dental healthcare treatment performed in the hospital operating room.

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[6] Henderson, Dr. David K. "Postexposure Chemoprophylaxis for Occupational Exposures to the Human Immunodeficiency Virus." *Journal of the American Medical Association.* Vol. 281, No.10. 10 March 1999, page 931.

APPENDIX D

THE INTERESTS OF THE HEALTH OF THE PRACTICING DENTIST WHO PERFORMS INVASIVE DENTAL PROCEDURES FOR KNOWN PATIENTS WITH HIV INFECTIOUS DISEASE

1) Common knowledge concerning the hospital operating room option when planning invasive dental healthcare procedures for a patient with HIV infectious disease:

Historically, the hospital was designed to prevent the spread of infectious disease from infected patients to non-infected people—healthcare workers included.

It is common knowledge that the hospital operating room offers a sanctuary from the distractions of the everyday fast-paced dental office. Physicians have traditionally opted for the operating room instead of their private offices for a variety of reasons, including the less stressful and safer environment.

Without the stress and distractions of the dental office to contend with, the dentist and dental assistant are better able to concentrate on the treatment procedure and take the necessary time to reduce potential accidental occupational exposures to HIV infectious disease.

In 1994, Dr. Bragdon believed and the American Association of Forensic Dentists and Clinical Research Associates concurred, that the hospital operating room could help healthcare workers provide better invasive dental healthcare services for patients with HIV infectious disease in a safer manner, minimizing needle-stick and other occupational exposures to HIV.

2) Scientific findings prove that the hospital operating room is a reasonable option for the dentist in which to invasively treat known patients with HIV infectious disease.

The American Dental Association states there is no evidence of HIV transmission from infected patients to dentists. This overstates the case. There is indeed evidence of HIV transmission, but no scientific proof of it. This is because so few dentists have been enrolled in the requisite prospective studies (essential for documentation) that only 19 exposures have been documented.[7] Since only one exposure in 300 is thought to transmit HIV, it is not surprising that no transmissions to dentists have been documented, including the seven possible transmissions to dentists that are listed in the CDC's HIV/AIDS Surveillance data. OSHA has reported the potential for HIV transmission due to a single contaminated needle stick is 3 to 4 per 1,000.[8] Dr. David Bell, the CDC's Director for the HIV Infectious Programs, has reported that the risk of getting HIV infectious disease from some hollow-bore needle stick injuries is 5%.[9] Sanford Kuvin, M.S., M.D., D.T.M.&H, Dr. Bragdon's expert witness, testified that a reasonable estimate of the risk that a dentist will accidentally contract HIV infectious disease when giving a single intra-oral injection (shot of local anesthesia) to an HIV-infected patient is 1 in 66,667. Dr. Kuvin further testified that if a dentist gives an average of one intra-oral injection each working day to a patient with HIV infectious disease for thirty years, the dentist has a 1 in

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[7] "Percutaneous Exposures to HIV Infected Blood." *Journal of the American Dental Association.* Vol. 126. September 1995, page 1237.

[8] "Occupational Exposure to Bloodborne Pathogens: Final Rule." *Federal Register.* Vol.. 56, No. 235. Dec. 6, 1991, page 64090.

[9] *Amicus* Brief of Defendant/Appellant Randon Bragdon, D.M.D., to the United States Court of Appeals for the First District, on Remand from the United States Supreme Court, pages 5 and 6.

10 risk of accidentally contracting HIV infectious disease during the lifetime of the practice.[10] The CDC has reviewed several studies and concluded that dentists traditionally have a high rate of needle stick injuries (2-15 injuries per month per dentist).[11]

In 1994, injury with HIV infected instruments (e.g. needle sticks) was considered significant by many members of the medical community. "It is becoming clear that the risk of occupational HIV exposure may be significant."[12]

3) The courts should not consider additional prudent precautions, which can protect the health of dentists, as discriminating against known patients with HIV infectious disease.

There are many other additional prudent precautions, besides the hospital operating room option, which dentists have available. Some of these are: using only sharp single-ended instead of double-ended instruments, or double gloves instead of single, or treating these patients at the start or end of a work day instead of during high traffic hours in their dental office, or suspending the use of aerosol producing instruments, or the utilization of high volume evacuation under laminar flow conditions with hood or full face protection and remote air source for the operator.

Dentists are concerned that these prudent additional precautions may be considered by the courts to be discriminatory. Therefore, they can be fearful of legal

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[10] *Ibid.*

[11] Ciesielski, C. "Transmission of HIV in a Dental Practice." *Annals of Internal Medicine.* Vol. 116, No. 10. May 15, 1992, pages 798-805.

[12] Hermann, Richard C. "Risks of HIV Exposure to Medical Students and Health Care Personnel." *Journal of the American Medical Association.* Vol. 264, No. 9. 1990, page 1187.

consequences of implementing them. This affects the health interests of many dentists who desire to use these other prudent additional precautions. The "direct threat' issue of this case directly relates to the use of these other additional prudent precautions.

Because of concern for the non-efficacy of universal precautions, the lack of sound scientific determinations concerning "degree of risk," and the concern for needle-stick and other occupational exposures when invasively treating patients with HIV infectious disease, Dr. Bragdon was reasonable when he suggested to Ms. Abbott that she have her invasive dental healthcare procedures performed in the hospital operating room. Post-exposure prophylaxis drug science further validates Dr. Bragdon's, or any dentist's, decision to recommend the additional precaution of the operating room for the invasive treatment of known patients with HIV infectious disease.

ADDENDUM

PROFESSIONAL RESUMES OF ADDITIONAL AMICI

1. Congressman Charles Norwood, D.D.S., represents Georgia's 10th Congressional District. He has served as President of both the Georgia Dental Association and the Eastern District Dental Society, was elected as a Delegate to the American Dental Association in 1984-85, and was founder of the Augusta Dental Disaster Society. He remains a member of the American Dental Association, the Georgia Academy of Dental Society, the Augusta Dental Society, is an Honorable Fellow of the Georgia Dental Association, and a Fellow of both the International College of Dentistry and the American College of Dentistry Sciences.

2. Congressman Tom Coburn, M.D., represents Oklahoma's 2nd Congressional District in the U.S. House of Representatives. A practicing physician, Coburn is a Member of the Committee on Commerce where he serves as the Vice-Chairman of the subcommittee on Health & Environment. He graduated the University of Oklahoma Medical School in 1983. Coburn is a resident of Muskogee, Oklahoma, where he specializes in family medicine and obstetrics. Dr. Coburn and his associates serve more than 10,000 patients.

3. The American Association of Forensic Dentists (AAFD) is an international association of dental, medical, human biology and law enforcement professionals organized in 1978 to promote scientific and sound treatment of diseases, human identification, epidemiology and legal matters related to the field of dentistry. The AAFD's membership rolls number approximately 3,000. The American Association of Forensic Dentists previously

submitted an *Amicus Curiae* brief in support of Dr. Bragdon to the United States Court of Appeals for the First Circuit.

4. The Association of American Physicians and Surgeons, Inc. is a national association of over 5,000 physicians of all specialties, founded in 1943 to preserve and promote the practice of private medicine in the tradition of Hippocrates.

5. Dentists for Preservation of Professional Judgement is an organization founded in April, 1997, and composed mostly of American Dental Association members and other healthcare related individuals. Dentists for Preservation of Professional Judgement previously submitted an *Amicus Curiae* brief in support of Dr. Bragdon to the United States Court of Appeals for the First Circuit.

6. E.J. Neiburger, D.D.S., is Director of the Center for Dental AIDS Research, Past Scientific Chairman of the Illinois State Dental Society, Past Chairman of the St. Therese Hospital Dental Staff, Vice President of the American Association of Forensic Dentists, and Editor of the Journal of the American Association of Forensic Dentists since 1979.

7. Cary Savitch, M.D., is an assistant clinical professor of medicine at UCLA, and a Fellow in the American College of Physicians. He has practiced medicine since 1977. Throughout his medical career, he has specialized in the study and treatment of infectious diseases. In particular, from his infectious disease specialty training at the San Francisco General Hospital in 1979-1980 up to

the present, he has studied both HIV and AIDS and has treated and consulted on hundreds of patients with AIDS and/or HIV. Dr. Savitch previously submitted an *Amicus Curiae* brief in support of Dr. Bragdon to the United States Court of Appeals for the First Circuit.

8. Stephen D. Carter, D.D.S., is a member of the American Dental Association, Georgia Dental Association, the Northern District Dental Society of Georgia, and the Pierre Fouchard Academy. He is a dentist-researcher who holds three patents related to infection-control related research: for Basic research in heat independent autoclaving utilizing agents in conjunction with increased pressure and ultrasonic transient cavitational collapse; Basic research in compression/ supersaturation/explosive decompression of microbes for germicidal effect; and for Basic research and development of the Kleen system of disinfecting writing instruments in the healthcare setting. He has had numerous articles published on infection control related subjects. He has 32 years experience as a practicing dentist. He is an Honorable Fellow of the Georgia Dental Association.

9. John L. Kennedy, D.D.S., is a member of the American Dental Association, the New Mexico Dental Association, and the Laguna Beach, Ca. Dental Study and Think Tank Group. He was a contributing Editor to "Dental Economics" magazine from 1989-1997. He was President of the Baylor College of Dentistry Alumni Organization for 1996-97 and a Honors Graduate of Baylor University College of Dentistry 1964. He is a Consultant for Mercer International and has had 31 years experience in the private practice of Dentistry.

10. Charles E. Smith, D.M.D. is a Member fo the American Board of Dental Examiners, a Member of the Alabama Board of Dental Examiners, a Past President of the Third District Dental Society, a component of the Alabama Dental Association which is a constituent of the American Dental Association. He has had 32 years experience as a practicing General Dentist.

11. Brian E. Eifert M.D. is a member of the Roentgen Ray Society, the Association of American Physicians and Surgeons, the Society of Nuclear Medicine, and is President-Elect of the Mississippi Society of Nuclear Medicine. He is a practicing radiologist.

12. William J. Dubose, B.S, D.M.D. is a past President of the Alabama Dental Association, a constituent of the American Dental Association. He is a Fellow in the American College of Dentistry, a Fellow in the International College of Dentistry, and a Master in the Academy of General Dentistry. He has had 40 years experience as a practicing General Dentist.

13. Robert J. Gherardi, B.S., D.M.D., FAGD, FACD, FADI, is a member of the American Dental Association and served the Association as: Vice-Chairman of the Council on Dental Therapeutics in 1991, member of the Reference Committee on Scientific Matters in 1992, and Delegate from New Mexico from 1990-1998. He is a member of the Academy of Dentistry International, American College of Dentists, the New Mexico Board of Dental Health, the National Academy of General Dentistry, the New Mexico Dental Association, the Albuquerque District Dental Society, and is a past President of the New Mexico Academy of General Dentistry. He received the following fellowships: the Academy of General Dentistry in 1987, the Academy of Dentistry International in 1993, and the American

College of Dentists in 1996. He was listed in 1995 in "Who's Who" in American Dentistry. He has had 19 years experience in the private practice of general dentistry.